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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,211	03/08/2001	Bruce Bryan	24729-105G	7925

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08/13/2003

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EXAMINER

HELMER, GEORGIA L

ART UNIT

PAPER NUMBER

1638

12

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,211

Applicant(s)

BRYAN, BRUCE

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 11, filed 13 June 2003. Applicant elects Group I, claims 1 and 3, drawn to a combination comprising a transgenic plant that expresses luciferase and a plant food that comprises luciferin, and to claims 2 and 4, drawn to a transgenic plant that expresses luciferin and a plant food that comprises luciferin, with traverse. Applicant traverses this restriction but gives no grounds for the traverse. Since no grounds for the traversal are offered, this is treated as an election without traverse, and accordingly is made final.
2. Claims 1-10 are pending. Claims 1-4 are examined in this action. Claims 5-10 are withdrawn as being drawn to non-elected inventions. This restriction is made FINAL.

Priority

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

In the first line of the specification there are two paragraphs of continuing data, neither of which matches the bib data sheet, and neither of which appears to be completely correct. Correction is needed

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Information Disclosure Statement

4. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 6, filed 21 May 2001, is attached to the instant Office action.

Claim Rejections - 35 USC § 112-Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not reasonably provide enablement for a transgenic plant that expresses luciferin.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

The enablement issue is : *a transgenic plant that expresses luciferin.*

Applicant's claims are drawn to a combination comprising a transgenic plant that expresses luciferase and a plant food that comprises luciferin, and to a composition

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comprising a transgenic plant that expresses luciferin and a plant food that comprises luciferase, a plant food comprising a luciferase or luciferin, where the plant food is a fertilizer, or comprises a plant growth promoter.

The state of the art and the predictability or lack thereof in the art: The state of the art is that one of ordinary skill in the art can transform a plant with DNA vector constructs, depending on the particular plant and availability of the DNA to be used as the transforming agent, with reasonable expectation of success. However if appropriate DNA constructs or other source materials are not available, then it is unpredictable that the desired transgenic plant can be produced with reasonable expectation of success. Rather it is predictable that the desired transgenic plant will not be able to be produced.

In the instant case, Applicant claims a transgenic plant expressing luciferin. However, luciferin is not a protein, and therefore the introduction of a coding sequence for luciferin is not possible, since coding sequences only encode mRNA and proteins. Commercially available luciferin presently is isolated from various living organisms such as bacteria or fireflies, these organisms possess biosynthetic enzymes in a pathway for the production of luciferin. Or luciferin can be chemically synthesized. One skilled in the art would need to have available all the genes from a biosynthetic pathway for the production of luciferin. Once having these, the genes would need to be operably expressed in the desired transgenic plant in the proper sequence under conditions allowing production of the various enzymatic components of the biosynthetic pathway in the presence of all required precursors to produce luciferin.

Guidance and working examples: Applicant has provided no working examples of the claimed invention. While working examples are not required, Applicant must provide sufficient guidance to address the issues raised above. Without such guidance, the experimentation required would not be routine, but would be undue. Accordingly, Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

In view of the breadth of the claims (any transgenic plant, any luciferin, and any luciferase), the lack of guidance, the lack of working examples, the unpredictability of the art, undue trial and error experimentations would be required to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Firoozabady et. al., US 5,480,789, issued 2 January 1996.

Firoozabady teaches an ornamental plant (column 18, Table 3, and column 19 lines 23-45) that expresses luciferase (Figure 3 and column 2 lines 62 bridging to

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column 3, line16) and a plant food comprising luciferin (column 2 lines 62 bridging to column 3, line16).

Applicant's limitation of "wherein the combination is a novelty item" is an intended use and therefore is given no patentable weight. Applicant's specification defines plant food as "any liquids... applied to a plant to promote or maintain growth" (column 72, lines 34-41) which encompasses water.

Accordingly Firoozabady anticipates the claimed invention.

Remark

9. No claim is allowed.

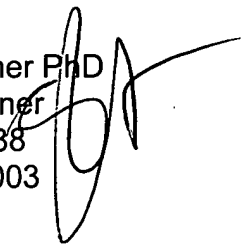
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196

Georgia Helmer PhD
Patent Examiner
Art Group 1638
August 11, 2003



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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